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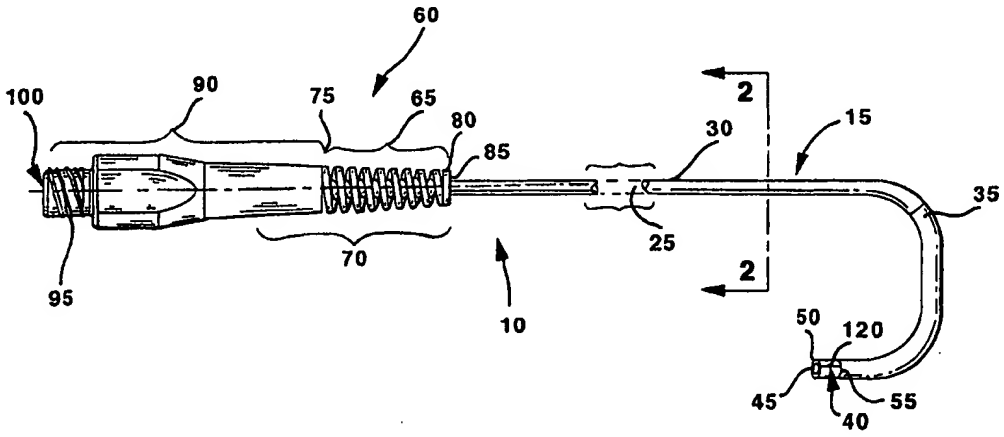

(57) Abstract

Medical vascular catheters adapted to be inserted into a blood vessel from an incision through the skin of a patient for introducing other devices or fluids for diagnostic or therapeutic purposes into the patient's vasculature and manufacturing methods are disclosed. The catheters have an extruded soft tip attached to the distal end of the catheter body that has one or more longitudinally extending radiopaque stripe formed therein by co-extrusion with the non-radiopaque portion of the soft tip. Preferably, each such radiopaque stripe is embedded within the polymer that merges to form the inner lumen surface and the outer tube surface, so that the particles of radiopaque powder material are substantially encased in the polymer material to provide smooth lumen and outer tube surfaces. The embedded strip cross section can be circular or arcuate, depending on the shape of the extrusion jet bore used to inject the blend of radiopaque material and polymer. Alternatively, the radiopaque stripes of any shape can extend to either one or both of the outer tube surface and the inner lumen surface. A low concentration of the radiopaque material can be included in the polymer forming the entire side wall of the extruded tube so that the entire distal soft tip exhibits faint radiopacity when viewed under fluoroscopy, but the radiopaque stripes exhibit are stronger radiopacity.

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CATHETER HAVING EXTRUDED RADIOPAQUE STRIPES EMBEDDED IN SOFT TIP AND METHOD OF FABRICATION

CROSS-REFERENCE TO RELATED PENDING APPLICATIONS

Reference is made to commonly assigned U.S. Patent Application Serial No. 09/021,682 filed February 10 1998, for SINGLE PIECE HUB/STRAIN RELIEF THAT CAN BE INJECTION MOLDED OVER A SHAFT in the names of Ghaleb A. Sater et al.

FIELD OF THE INVENTION

The present invention relates to medical vascular catheters adapted to be inserted into a blood vessel from an incision through the skin of a patient for introducing other devices or fluids for diagnostic or therapeutic purposes. More particularly, the present invention is directed to a catheter having an extruded soft tip attached to the distal end of the catheter body that has one or more longitudinally extending radiopaque stripe formed therein by co-extrusion with the non-radiopaque portion of the soft tip and a method of attachment of the distal soft tip to the catheter body.

BACKGROUND OF THE INVENTION

Catheters are tube-like medical instruments that are inserted into a body cavity organ or blood vessel for diagnostic or therapeutic reasons. Medical vascular catheters are particularly designed for insertion into the vasculature and are available for a wide variety of purposes, including diagnosis, interventional therapy, drug delivery, drainage, perfusion, and the like. Medical vascular catheters for each of these purposes can be introduced to numerous target sites within a patient's body by guiding the catheter through an incision made in the patient's skin and a blood vessel and then through the vascular system to the target site.

Medical vascular catheters generally comprise an elongated, flexible catheter tube or body with a catheter side wall enclosing a catheter lumen extending between a catheter body proximal end coupled to a relatively more rigid catheter hub to a catheter body distal end. The catheter body may be relatively straight or inherently curve or curved by insertion of a curved stiffening wire or guide wire through the

catheter lumen. The catheter body and catheter side wall are typically fabricated and dimensioned to minimize the catheter body outer diameter and side wall thickness and to maximize the catheter lumen diameter while retaining sufficient side wall flexibility and strength characteristics to enable the catheter to be used for the intended medical purpose.

In the therapeutic procedure known as percutaneous transluminal coronary angioplasty ("PTCA"), thin wall vascular catheters are used to guide the introduction of balloon angioplasty catheters to an obstruction in a blood vessel. PTCA catheter shafts must have lumens large enough to receive the balloon angioplasty catheters and have sufficient shaft stiffness to be pushed through vessels and rigidity to provide a high degree of torsional control. Stiffness or rigidity in the PTCA catheter tip poses the danger of puncturing or otherwise damaging a vessel as it is advanced through the vascular system. It is therefore desirable for such catheters to have a flexible distal soft tip as explained in commonly assigned U.S. Pat. No. 5,509,910, issued to Lunn and incorporated herein by reference.

A number of techniques for joining a distal soft tip tube segment to or extending a softer tube extension from the distal end of the catheter body or shaft are set forth in the `910 patent. Such techniques include the steps of: (1) separately fabricating the distal soft tip tube of much softer and more flexible material dimensioned to share the OD and lumen ID, and hence the side wall thickness, of catheter shaft; (2) cutting it into tube segments approximating the desired distal soft tip length; (3) butt or overlap welding or adhering the separately fabricated tube segment to the distal end of the catheter shaft; and (4) trimming the distal soft tip to the specified length. As explained in the `910 patent, the trend toward thin wall catheter shafts with side wall thickness of less than 0.3 mm results in an extremely small butt weld area and substantially weaker bond between the catheter shaft and the tube segment when joined together. The `910 patent discloses inventive catheter fabrication methods and structures that overcome the problem of low bond strength between the catheter shaft and soft distal tip created by catheters with wall thickness of less than 0.3 mm and use of a highly flexible and soft distal tip material.

In the preferred embodiments disclosed in the '910 patent, the surface geometry of both the distal end of the catheter shaft and the distal tip tube segment are modified to reduce stress concentration and increase surface area so that the adequate bonding is achieved therebetween. The modified surface geometry on the distal end of the catheter shaft is created by removing two ungular sections on either side of the central longitudinal axis of the catheter shaft. Similarly, the surface geometry on the proximal end of the separately fabricated tube segment is modified by removing two mating ungular sections on either side of the central longitudinal axis of the tube segment that is to be bonded to the catheter shaft. An alternative embodiment involves removing more than two ungular sections on either or both of the distal end of the catheter shaft or the proximal end of the soft tip tube segment to further promote bonding. The mating ungular sections of the catheter shaft distal end and the distal soft tip tube segment proximal end are fitted together like jig saw puzzle pieces and adhesion is effected in a heated molding process.

In a further aspect of the inventive structure and methods disclosed in the '910 patent, a high tensile strength transition segment, selected from a group of thermoplastic elastomers having an ultimate tensile strength of at least 45 MPa is employed between the distal end of the catheter shaft and the distal soft tip tube segment. The adhesion of the transition segment with the distal end of the catheter shaft and the proximal end of the distal soft tip tube segment is effected also employing mating ungular sections and the heated molding process.

In the use of such vascular catheters in PTCA procedures and in other medical procedures, it is desirable for the physician to use fluoroscopy to visualize the progress of the catheter shaft during advancement in the vascular system and particularly to observe the position of the catheter distal tip. The catheter shafts of such thin wall vascular catheters are frequently formed of materials that are not radiopaque or have poor radiopacity when viewed under fluoroscopy. Therefore, it has been proposed to make the catheter shaft and/or the distal tip radiopaque in some fashion, e.g., by the incorporation of one or more metal ring or wire coil of platinum or the like into the side wall between the distal end of the catheter shaft and the distal

soft tip. It is also known to add radiopaque materials to the materials forming the distal soft tip to impart radiopacity. For example, U.S. Patent No. 5,171,232 issued to Castillo et al. describes adding a number of radiopaque agents to the material of the distal soft tip and then extruding a distal soft tip tube segment of the blended materials. When the distal soft tip is formed of a polyurethane or polyether-polyurethane or polyester-polyurethane blends, it is proposed to add 50%-70% by weight of a radiopaque agent of bismuth trioxide, for example, to the blend. The blended material is extruded into the distal soft tip tube segment which is cut and butt welded to the catheter shaft. Preferably, an intermediate tube segment is also butt welded end to end between the distal soft tip tube segment and the catheter shaft. In either case, the distal soft tip exhibits uniform radiopacity and provides the appearance of a radiopaque ring when viewed under fluoroscopy. Radiopaque distal soft tips are formed in similar fashions as described in U.S. Patent Nos. 5,584,821 issued to Hobbs et al. and 5,234,416 to Macaulay et al. In the `416 patent, the radiopaque ring is formed in the intermediate tube segment between the distal soft tip and the catheter shaft.

The addition of radiopaque materials blended with the soft tip polymer in the stated concentrations required to make the distal soft tip or a ring adjacent to the distal soft tip sufficiently visible under fluoroscopy tends to make the distal soft tip side wall less flexible and to defeat its primary purpose. In addition, it becomes more difficult to butt weld the distal soft tip proximal end to the catheter shaft or transition segment distal end because of the lowered concentration of the polymer in the blend.

In other catheters that have "hard" plastic tips, it has been proposed to glue radiopaque metal stripes along the sides of the catheter shaft extending proximally from the distal tip to aid in visualizing rotational and axial positioning of the catheter as described in U.S. Patent Nos. 5,041,108 and 4,848,336 issued to Fox et al. In U.S. Patent No. 5,429,617, issued to Hammersmark et al., it has also been proposed to add axially extending notches or projections to a metal ring type radiopaque tip marker to provide axial, rotational, and yaw visualization under fluoroscopy to aid in aligning a

laser catheter tip in angioplasty procedures. The epoxy laser lens fills the catheter lumen to the catheter distal tip, and consequently the distal tip is not a distal soft tip.

It is also known to extrude relatively soft catheter bodies for other uses that have stripes of radiopaque material extruded with the shaft material and extending along the length of the catheter body as shown in U.S. Patent Nos. 4,657,024, issued to Coneys, 4,469,483, issued to Becker et al., and 5,456,674, issued to Bos et al. The radiopaque powder material, e.g., barium sulfate or bismuth trioxide is blended with a small percentage by weight of the polymer material used to fabricate the catheter body so that it binds with the polymer material of the catheter body. The straight or spiral stripes are formed by co-extrusion in a manner shown with particularity in the `674 patent, which is incorporated by reference herein. These patents disclose catheter bodies that are fabricated by extrusion through their entire lengths.

Despite the considerable effort in designing distal soft tips for relatively stiff vascular catheter shafts and methods of attachments therebetween, there is still room for improvement particularly in economically providing radiopaque markers.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide a simple, inexpensive and reliable distal soft tip having a radiopaque stripe incorporated therein for providing the advantages of retaining soft tip flexibility while allowing the physician to clearly visualize the distal end of the soft tip of he catheter to confirm position and torque transfer.

It is a further object of the invention to provide such a distal soft tip that can be readily extruded as a distal soft tip segment in side wall dimensions to conform with the catheter shaft dimensions and with co-extruded radiopaque stripes shaped and located therein in a variety of configurations.

It is a still further object of the invention to provide such a distal soft tip segment with co-extruded radiopaque stripe(s) and attachment method with the distal end of the catheter shaft or a transition segment that is inexpensive to manufacture.

The present invention is directed to a vascular catheter, e.g. a PTCA guiding catheter, comprising an elongated catheter body and a catheter hub formed of a thermoplastic hub material receiving and adhered to a proximal portion of said catheter body in an elongated catheter hub/body junction thereof. The elongated catheter body has a thin catheter body side wall surrounding a catheter lumen and extending between a catheter body proximal end and a catheter body distal end. In one embodiment, the catheter body further comprises a relatively stiff catheter shaft extending from said catheter hub/body junction to a catheter shaft distal end and a flexible, non-traumatic, distal soft tip adhered to the distal end of the catheter shaft. In another embodiment, a high tensile strength, transition segment is bonded to the catheter shaft distal end and to the proximal end of the flexible, non-traumatic, distal soft tip. In all embodiments, the distal soft tip incorporates one or more stripe of radiopaque material co-extruded with the material of the distal soft tip prior to its attachment to the distal end of the catheter shaft or transition segment.

The catheter shaft is preferably formed with a thin side wall formed of an outer tubular sheath, an inner tubular sheath, and a wire braid tube sandwiched between the outer and inner tubular sheathes and has a side wall crush resistance of about 2-7 pounds.

In practice, preferably the surface geometry of the ends of the elongated tubular catheter shaft, distal soft tip tube segment and the transition segment (if used) are modified to reduce stress concentration and increase surface area so that the adequate end-to-end bonding is achieved. The use of the modified surface geometry of the ends that are mated together substantially increases the tensile strength of the bond between the catheter shaft and the distal soft tip. The use of a high tensile strength, transition segment coupled with the modified surface geometry of the ends further increases the tensile strength of the bond between the catheter shaft and the distal soft tip.

In the preferred embodiment, the applicant creates a modified surface geometry on the distal end of the catheter shaft by removing two or more ungular sections on either side of the central longitudinal axis of the catheter shaft. Similarly,

the surface geometry on the proximal end of the distal soft tip tube segment is modified by removing two or more mating ungular sections on either side of the central longitudinal axis of the tip segment. The ungular sections of the catheter shaft distal end and the distal soft tip proximal end are aligned and interlock together to form a butt weld zone for adhesion of the contacting ungular sections. The same approach is employed when the transition segment is included between the catheter shaft distal end and the distal soft tip proximal end .

The distal soft tip tube segment is preferably formed of an extruded tube having an inner lumen, side wall thickness and outer diameter that matches the like dimensions of the catheter shaft or the transition segment that is cut into distal soft tip tube segments prior to attachment with the catheter shaft or transition segment.

The soft tip tube is extruded employing a selected polymer in an extruder that meters a coating of a polymer onto a solid circular core. The radiopaque stripe or stripes are co-extruded employing one or more of the extrusion jets located at specified angles to one another to inject a narrow stream of a blend of radiopaque powder material and the selected polymer that forms the radiopaque stripe in the side wall of the tube. In the co-extrusion process, one or more radiopaque stripe can be formed that each extend substantially parallel with the axis of the tube and one another. Alternatively, the extruded distal soft tip tube can be rotated as the co-extrusion takes place to form one or more spiral stripe of the radiopaque material.

Preferably, each such radiopaque stripe is embedded within the polymer that merges to form the inner lumen surface and the outer tube surface, so that the particles of radiopaque powder material are substantially encased in the polymer material to provide smooth lumen and outer tube surfaces. The embedded strip cross-section can be circular or arcuate, depending on the shape of the extrusion die used to inject the blend of radiopaque material and polymer. Alternatively, the radiopaque stripes of any shape can extend to either one or both of the outer tube surface and the inner lumen surface.

In a further variation, a low concentration of the radiopaque material can be included in the polymer forming the entire side wall of the extruded tube so that the

entire distal soft tip exhibits faint radiopacity when viewed under fluoroscopy. The radiopaque stripes are distinguished by having a higher concentration of the radiopaque material so that the radiopaque stripes can be seen within the faint radiopaque image of the soft distal tip.

Additional transition segments can also be employed in the construction of the catheter body in accordance with the invention.

The catheter of the present invention is preferably formed by extruding a distal soft tip tube, cutting the distal soft tip tube into a distal soft tip tube segment, modifying the surface geometry of the proximal end of the distal soft tip tube segment and the distal end of either the catheter shaft or the transition segment, bonding the proximal end of the distal soft tip tube segment and the distal end of either the catheter shaft or the transition segment together, and, if necessary, trimming the distal end of the distal soft tip tube segment to form a distal soft tip of a specified length.

The radiopaque soft tip formed in this manner has a number of advantages in use. The radiopaque stripes allow the physician to clearly denote the distal end of the distal soft tip, thus reducing the possibility of inadvertent balloon inflation or stent deployment inside the lumen of the guide catheter. Rotational movement of the radiopaque stripes can be seen under fluoroscopy while the proximal end of the guide catheter is rotated or twisted. In this way, the physician can be assured that the rotational or twisting torque is transferred distally down the catheter body to the distal soft tip. The enhanced ability to observe torque transfer and advancement of the catheter distal soft tip reduces the time that it takes to position the distal soft tip at a desired site in the vascular system.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a plan view of an exemplary medical vascular catheter constructed a the distal soft tip incorporating one or more radiopaque stripe in accordance with a preferred embodiment of the invention;

FIG. 2 is an enlarged cross-section view of the relatively stiff catheter shaft taken along lines 2-2 in FIG. 1;

FIG. 3 is a perspective view of a section of the relatively stiff catheter shaft peeled back to reveal an inner tubular sheath, an outer tubular sheath and a wire braid tube sandwiched between the inner and outer tubular sheathes;

FIGs. 4-9 are end views of the distal soft tip of FIG. 1 depicting cross-section shapes of exemplary embodiments of the one or more straight or spiral radiopaque stripes co-extruded into the side wall of the distal soft tip in accordance with the invention;

FIG. 10 is a perspective view of a length of distal soft tip tube extruded from a soft polymer and incorporating two radiopaque stripes formed by co-extrusion of a blend of radiopaque material with the polymer and similar in cross-section configuration to the radiopaque stripes;

FIG. 11 is a perspective view of a distal soft tip tube segment cut from the distal soft tip tube of FIG. 10 with ungular cut sections of the distal soft tip proximal end;

FIG. 12 is an end view of the distal soft tip tube segment cut from the distal soft tip tube of FIG. 10 displaying the ungular cut sections;

FIG. 13 is a partial side view of the assembly of the distal soft tip tube segment and the catheter shaft distal end over a mandrel in aligned mating relationship of the respective ungular cut sections of the catheter shaft distal end and the distal soft tip proximal end;

FIG. 14 is a partial side view of the assembly of the distal soft tip tube segment and the catheter shaft distal end over the mandrel with the respective ungular sections interlocked together to form a butt weld zone and the application of heat, pressure and adhesive for effecting adhesion of the contacting ungular sections at the butt weld zone;

FIG. 15 is a partial side view of the resulting distal soft tip adhered to the catheter shaft distal end following completion of the process of FIG. 13;

FIG. 16 is a partial side view of the assembly of the distal soft tip tube segment, a transition segment, and the catheter shaft distal end over a mandrel in aligned mating relationship of the respective ungular cut sections of the catheter shaft distal end, the transition segment proximal and distal ends, and the distal soft tip proximal end;

FIG. 17 is a partial side view of the assembly of the distal soft tip tube segment, the transition segment, and the catheter shaft distal end over the mandrel with the respective ungular sections interlocked together to form two butt weld zones and the application of heat, pressure and adhesive for effecting adhesion of the contacting ungular sections at the butt weld zones;

FIG. 18 is a partial side view of the resulting distal soft tip adhered to the transition segment and the transition segment adhered to the catheter shaft distal end following completion of the process of FIG. 17;

FIG. 19 is a partial side view of the distal end of the catheter of FIGs. 15 and 18 rotated 90°; and

FIG. 20 is a partial side view of the distal end of the catheter of FIGs. 15 and 18 illustrating an alternative manner of making the mating ungular cuts.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides an improved construction for catheters of the type having an elongated catheter body with at least one catheter lumen extending from catheter body proximal end to a catheter body distal end thereof, and having a soft distal tip. Such constructions are particularly useful for forming medical vascular catheters in a wide range catheter body lengths and outer diameters. Such catheters include small diameter vascular catheters, having catheter body outside diameters of 4 mm (12 F) preferably below 2.67 mm (8 F), and frequently as small as 1 mm (3 F), and below, such as those used in neurological diagnostic and interventional procedures. Such small diameter vascular catheters will also be useful for other procedures, such as gynecological procedures, cardiac procedures, general interventional radiology procedures, and the like, for access to the small vasculature as necessary. Constructions of the present invention, however, are not limited to such small diameter catheters, and will be useful for larger diameter catheters as well, such as vascular guiding catheters and PTCA balloon catheters which may have outside diameters larger than 4 mm.

Medical vascular catheters according to the present invention will comprise a catheter body having dimensions, a particular side wall construction and a geometry selected for the intended use. The catheter body will typically have a length in the range from about 40 cm to 200 cm, usually having a length in the range from about 60 cm to 175 cm. The outside diameter of the catheter body will typically be in the range from about 0.33 mm (1 F) to 4 mm (12 F), usually being in the range from about 0.66 mm (2 F) to about 3.33 mm (10 F). The catheter body will define an inner lumen typically having a diameter in the range from about 0.1 mm to 3.6 mm, usually being in the range from about 0.3 mm to 3.0 mm, with catheters having larger outside diameters usually having larger catheter lumen diameters.

FIG. 1 is a plan view of an exemplary medical vascular catheter 10 constructed with the unitary catheter hub and strain relief 60 coupled along a catheter hub/body junction 70 with a proximal end segment of the catheter shaft 30 of the catheter body 15 as described in detail in the above-referenced `682 application. The unitary catheter hub and strain relief 60 is injection molded as a single piece over the catheter hub/body junction 70 and includes a proximal hub portion 90 and a strain relief coil 65. The hub portion 90 surrounds and defines a hub lumen 100 extending to the lumen 25 of the catheter body 15. The proximal hub portion 90 is integrally connected to the proximal strain relief coil end 75 of the strain relief coil 65. The strain relief coil 65 is a continuous coil of constant or variable pitch having coil turns that decrease in diameter from the proximal strain relief coil end 75 to the distal strain relief coil end 80. The turns of the strain relief coil 65 are preferably molded over a distal portion of exterior surface of the catheter body 15 in the catheter hub/body junction 70 and adhered in a spiral pattern to the exterior surface of the catheter body. In this manner, a strain relief coil lumen 85 is effectively formed because the distal portion of exterior surface of the catheter body 15 extending the length of the catheter hub/body junction 70 functions as a mandrel.

The catheter body 15 will usually be straight along all or most of its length, that is it will assume a straight or linear configuration, when free from external bending forces. The catheter body 15, however, will be highly flexible so that it will

be able to pass through the tortuous twists and turns of a patient's vasculature. In some cases, the catheter body 15 may have a shaped distal end segment including curves and bends which are selected to facilitate introduction and placement of the catheter 10 (usually over a separate guide wire) in the vascular system. A particular geometry of curves and/or bends may be selected to accommodate the intended use of the catheter 10.

In a broad overview of the present invention, the catheter body 15 comprises at least a proximal catheter shaft 30 and a distal soft tip 40, and the catheter shaft 30 may be constructed in any acceptable manner to provide desired characteristics. However, the catheter body 15 can also comprise at least one and at times more than one transition segment 35, wherein each the transition segment has a different construction resulting in different mechanical properties. For example, the catheter body 15 can be constructed to have flexibility that increases distally. FIG. 1 is intended to encompass any such construction, but will be described in particularity in reference to such catheter bodies that do have at least one transition segment 35 and do not have the transition segment 35 between the catheter shaft 30 and the distal soft tip 40.

In FIG. 1, a proximal catheter shaft 30 may extend from the unitary catheter hub and strain relief 60 to a location spaced within 20 cm of the catheter body distal end 50, usually from 2 cm to 6 cm of the catheter body distal end 50. The proximal catheter shaft 30 is preferably reinforced in catheter shaft side wall 20 as described below to have sufficient column strength and hoop strength for advancement through the incision in the patient's skin and blood vessel and through the tortuous vasculature. It will be understood that catheter shaft 30 can be constructed in other ways than specifically described below to achieve this end. However catheter body 30 is constructed, the construction makes it relatively stiff and capable of perforating a blood vessel wall if the catheter shaft distal end is aimed against it and advanced. The distal soft tip 40 is intended to offset that capability.

In one embodiment, the distal end of the catheter shaft 30 coupled directly with the proximal end of the distal soft tip 40 at a butt weld zone 55 as described below. The distal soft tip 40 is tubular and has a side wall that surround a soft tip

lumen that is the distal part of the catheter body lumen 25 and terminates at the distal lumen end opening 45. The distal soft tip 40 will generally be relatively short, typically having a length in the range from about 1.0 mm to 3.0 cm. The side wall of the distal soft tip 40 is flexible enough that the side wall can buckle slightly when it bears against a blood vessel side wall and will not perforate the blood vessel side wall.

In the three segment embodiment of the catheter body 15, a transition segment 35 is located immediately distally of catheter shaft distal end at butt weld zone 220 at a location spaced within 30 cm of the catheter body distal end 50, usually from 1 cm to 10 cm of the catheter body distal end 50. In this embodiment, the distal soft tip 40 extends distally from the distal end of the transition segment 35 and is composed of a soft, un-reinforced material as described below. The transition segment 35 has an intermediate level reinforcement providing an intermediate level of stiffness, column strength, and hoop strength between the high levels of the catheter shaft 30 and the low levels of the distal soft tip 40. Consequently, the transition segment 35 has an intermediate level of side wall flexibility between the low level of flexibility of the catheter shaft 30 and the high level of flexibility of the distal soft tip 40. Moreover, the construction of the side wall of the transition segment 35 overcomes difficulty that can be encountered in making a reliable connection between the catheter shaft distal end and the soft tip proximal end due to use of particular side wall polymer materials of each and reinforcement materials employed in the fabrication of the catheter shaft side wall.

A preferred embodiment of the construction of the catheter shaft side wall 20 of the catheter shaft 30 is depicted in FIGs. 2 and 3. The catheter body shaft is preferably formed in the manner taught in commonly assigned U.S. Patent Nos. 5,676,659 and 5,509, 910, both incorporated by reference herein, and as disclosed in the above-referenced `682 application. In accordance with this preferred embodiment of the invention, at least the proximal catheter shaft 30 is formed of an outer tubular sheath 110, an inner tubular sheath 105, and a wire braid tube 105 embedded in a polymer and sandwiched between the outer and inner tubular sheathes 110 and 105.

Typically, the inner tubular sheath 105 is formed from a single material, preferably a lubricious polymer, such as a fluorocarbon (e.g., polytetrafluoroethylene (PTFE)), a polyamide (e.g., nylon), polyether block amides (PEBA), a polyolefin, a polyimide, or the like. It would also be possible to form the inner tubular sheath 105 as a laminate structure comprising a non-lubricious outer layer and an inner lumen surrounding layer or coating of a more lubricious material.

The wire braid tube 115 comprises "warp" and "woof" wire filaments braided in a fabric basket weave pattern wound to form a tube. The wire braid tube 115 may be woven directly over the inner tubular sheath 105 using conventional fabric weaving techniques. Or, the wire braid tube 115 may be woven over a mandrel using conventional braiding techniques and then fitted over the inner tubular sheath 105. In either case, the outer tubular sheath 110 is then fitted over the wire braid tube 115.

The wire filaments have a very small cross-sectional area while possessing sufficient tensile strength to undergo the braiding process. Preferably, round wire filaments of stainless steel, a shape memory alloy (e.g., Nitinol), polymeric fibers, or the like, are used. Stainless steel filaments having a round cross-section with a diameter in the range from 0.001 inch to 0.01 inch, preferably about 0.002 inches are particularly preferred.

The outer tubular sheath 130 is preferably formed of a variety of materials, preferably being composed of a thermoplastic material having a hardness in the range from 30 Shore A to 72 Shore D. Exemplary materials include polyamide polyether block amides (PEBA), polyurethanes, silicone rubbers, nylons, polyethylenes, fluorinated hydrocarbon polymers, and the like.

In one preferred embodiment, the proximal catheter shaft 30 constructed in this manner having an outer diameter of about 0.106 inches (2.69 mm), a catheter lumen inner diameter of about 0.086 inches (2.18 mm) and a side wall of 0.010 inches (0.25 mm). Such a catheter shaft 30 has a hoop strength or crush resistance to a load of 2-7 pounds applied perpendicular to its longitudinal axis. The catheter body also exhibits an elastic modulus of between 28, 000 psi and 40, 000 psi under standard axial load conditions. The catheter body formed of the outer, inner and wire braid intermediate

sheathes also has a kink resistance which enables it to withstand a load of 0.5 pounds moment weight for a minimum deflection of 30° before the side wall kinks.

When the transition segment 35 is used, the selection of materials for the transition segment 35 is based upon considerations of tensile strength, processing temperature compatibility with the polymers comprising the catheter shaft 30, and flexural modulus. The materials are selected to result in a minimum tensile strength that depends on the outer diameter and wall thickness of the catheter body. A tensile strength in excess of 45 Mpa is necessary to achieve a minimally acceptable bond strength of 18N between the catheter shaft 30 and the transition segment 35 when the wall thickness of the catheter shaft is less than 0.3 mm, as in the above example. This is because of the compromised bonding between the catheter shaft 30 and the transition segment 35 caused by the presence of the wire braid tube 115 and the lubricious inner tubular sheath 105. The transition segment 35 does not bond to the lubricious inner sheath 105 or to the polymer that the wire braid of wire braid tube 115 is imbedded in. This is a consequence of the primary bonding mechanism being melt fusing. Since the wire cannot be melt fused to the transition segment 35, bonding between the transition segment 35 and the wire braid tube 115 is limited to the interstitial sites which are occupied by the polymer of the outer tubular sheath 110.

However, the transition segment 35 can be bonded well at its abutting interface in butt weld zone 210 of FIG. 1 with the polymer of the outer tubular sheath 110 if the polymer materials are chosen to have melt compatibility. Primary bonding occurs only at this abutting interface, and because the outer tubular sheath side wall thickness is only approximately one third of the overall catheter side wall thickness, the transition segment material and construction must also be chosen for its tensile strength. The transition segment 35 must have a processing temperature which is compatible with that of the polymer of the outer tubular sheath 110 in order to bond adequately at the abutting interface. Further, the transition segment 35 must exhibit sufficient flexibility to facilitate the manipulation of the catheter body 15 through the patient's vasculature. Sufficient flexibility is achieved where the flexural modulus of the transition segment 35 is less than 250 MPa. To meet the above requirements, the

transition segment 35 is formed of a Shore 55 D PEBAX® polyether block-polyamide tube, for example, having an outer surface diameter and an inner lumen diameter matching those diameters of the catheter shaft. This material has a compatible processing temperature to the polymer of the outer tubular sheath 110, which is preferably comprised of Shore 70D PEBAX® polyether block-polyamide, for example. In some embodiments, the segment 35 does include a wire braid tube of the type described above embedded within the PEBAX® polyether block-polyamide tube and in other embodiments the wire braid tube is not incorporated into the PEBAX® polyether block-polyamide tube.

As described in detail below, fabrication of the catheter body 15 is completed by extruding a distal soft tip tube 170, cutting the distal soft tip tube into a distal soft tip tube segment 140, modifying the surface geometry of the proximal end of the distal soft tip tube segment and the distal end of either the catheter shaft 30 or the transition segment 35, bonding the proximal end of the distal soft tip tube segment and the distal end of either the catheter shaft 30 or the transition segment 35 together, and, if necessary, trimming the distal end of the distal soft tip tube segment to a specified length for the distal soft tip 40. The extruded distal soft tip tube 170 is preferably formed having an inner lumen, side wall thickness and outer diameter that matches the like dimensions of the catheter shaft 30 or the transition segment 35. In accordance with the present invention, the one or more radiopaque stripe 120 is co-extruded with the extrusion of the tubular side wall of the distal soft tip tube. Before describing that process in detail, the attributes of the soft tip tube side wall and the polymer materials apart from the radiopaque stripe(s) and materials will be described.

The selection of polymer materials for the distal soft tip 40 in relation to the polymer materials of the transition segment 35 is based upon considerations of flexural modulus and tensile strength. The flexural modulus is an indicator of the ability of the polymeric soft tip side wall to deflect adequately when the distal soft tip 40 contacts a wall of the patient's vasculature. The tensile strength must be sufficient to ensure an 18N minimum bond strength between the distal soft tip 40 and the transition segment 35. When the transition segment 35 is present, the minimum

tensile strength of the polymer material of the soft tip side wall when extruded to form the distal soft tip 40 is significantly less than that required for the transition segment 35. The proximal end of the distal soft tip and the distal end of the transition segment 35 can be bonded together through the full thickness of the side walls of. Thus, a lower tensile strength is allowable to achieve the minimum bond strength of 18 N. To meet the requisite tensile strength and flexural modulus criterion, polymer materials should be chosen for the transition segment 35 and distal soft tip 40 with a tensile strength ratio of greater than 1.25 and flexural modulus ratio of less than 15.0. The result of the material selections and the modified surface geometry of the distal end of the transition segment 35 and the proximal, mating end of the distal soft tip 40 is a bond in the butt weld zone 55 in excess of 18N. For a catheter wall thickness of less than 0.3 mm, a polymer exhibiting a minimum tensile strength of 30 MPa is required for the soft tip segment 35. These criteria are met with a material such as Shore 35 D PEBAX® polyether block-polyamide or preferably a blend of 75% by weight 35 D PEBAX® and 25% 55 D PEBAX®, for example.

In the case where the transition segment is not employed, the selection of polymer materials for the distal soft tip 40 in relation to the polymer materials of the catheter shaft outer tubular sheath 110 is also based upon considerations of flexural modulus and tensile strength. As noted above, the tensile strength must be sufficient to ensure an 18N minimum bond strength between the distal soft tip 40 and the outer tubular sheath 110 in the butt weld zone. Again, polymer materials should be chosen for the transition segment 35 and distal soft tip 40 with a tensile strength ratio of greater than 1.25 and flexural modulus ratio of less than 15.0. The result of the material selections and the modified surface geometry of the distal end of the transition segment 35 and the proximal, mating end of the distal soft tip 40 is a bond in the butt weld zone 55 in excess of 18N. For a catheter wall thickness of less than 0.3 mm, a polymer exhibiting a minimum tensile strength of 30 MPa is required for the soft tip segment 35. These criteria are met with a material such as Shore 40 D or Shore 35 D PEBAX® polyether block-polyamide or preferably a blend of 75% by weight 35 D PEBAX® and 25% 55 D PEBAX®, for example. These materials have

a compatible processing temperature to the polymer of the outer tubular sheath 110, which is preferably comprised of Shore 70D PEBAX® polyether block-polyamide.

In accordance with the present invention, the distal soft tip 40 is formed with at least one co-extruded radiopaque stripe 120 formed in the side wall thereof and extending generally straight or in a spiral between the distal soft tip proximal and distal ends. The radiopaque stripe 120 is preferably formed of a radiopaque powder blended with the polymer material employed to form the distal soft tip tube. Such radiopaque powders include tungsten, tungsten dioxide, tungsten trioxide, barium sulfate, bismuth trioxide, stainless steel, silver iodide, or iodinated organic compounds as are and others known in the art. FIGs. 4-9 are end views of the distal soft tip 40 of FIG. 1 depicting cross-section shapes of exemplary embodiments of the one or more straight or spiral radiopaque stripes 120 - 135 co-extruded into the distal soft tip side wall 145 in accordance with the invention.

During the extrusion process of the distal soft tip tube, the injected polymer material merges together to form the soft tip side wall 145 between the inner soft tip lumen surface 195 and the soft tip outer surface 200. The radiopaque stripes are injected from one or more discrete radiopaque stripe blend injection nozzles spaced apart from one another to inject the blend of polymer and radiopaque material in discrete streams that are separated from one another by polymer material injected from other polymer material injection nozzles in a manner taught in the above-incorporated `674 patent. The extrusion jet bore of each radiopaque stripe blend injection nozzle or die is sized, shaped, and aimed to provide the desired cross-section of the radiopaque stripe.

The embedded radiopaque stripe cross-section can be arcuate, as shown by stripes 120 and 125 in FIGs. 4 and 8 or generally circular, as shown by stripes 120 and 125 of FIGs. 5, 6, and 7 and stripes 120-135 of FIG. 9. As shown in FIGs. 8 and 9, the radiopaque stripes can be embedded within the polymer that forms the soft tip lumen surface 195 and the soft tip outer surface 205. In this case, the radiopaque material is substantially encased in the polymer material to provide smooth soft tip lumen and outer tube surfaces 195 and 205. Alternatively, the radiopaque stripes of

any shape can extend to either one or both of the soft tip outer tube surface 200 and the inner lumen surface 195 as shown in FIGs. 4-7.

In a further variation usable in any of the configurations and shapes of FIGs. 4-9, a low concentration of the radiopaque material can be included in the polymer forming the entire side wall 145 of the extruded soft tip tube 170 so that the entire distal soft tip 40 exhibits faint radiopacity when viewed under fluoroscopy. The radiopaque stripes 120-135 are distinguished by having a higher concentration of the radiopaque material so that the radiopaque stripes 120-135 can be seen within the faint radiopaque image of the soft distal tip 40. FIG. 4 shows such a blend of a relatively low weight concentration blend of the radiopaque material and polymer forming a faintly radiopaque soft tip side wall 205. For example, the faintly radiopaque soft tip side wall 205 can be formed of a blend of PEBA with 40% by weight concentration of Ba SO_4, and the radiopaque stripes 120 and 125 can be formed of a blend of PEBA with 60% by weight concentration of tungsten powder.

The radiopaque stripes 120-135 can be of any number and various widths and are preferably straight and extend in parallel with the axis of the soft tip lumen 150. However, they can also be formed in interleaved spirals as depicted in FIG. 9 in a manner taught in the above-incorporated `674 patent. Any number of radiopaque stripes of these types can be incorporated into the distal soft tip 40.

FIG. 10 is a perspective view of a length of extruded distal soft tip tube 170 extruded from a soft polymer of the types described above and incorporating two radiopaque stripes 120 and 125 formed by co-extrusion of a blend of radiopaque material with the polymer and similar in cross-section configuration to the radiopaque stripes 120 and 135 of FIGs. 4-9, particularly FIG. 4. The radiopaque stripe 120 and 125 are co-extruded employing one or more of the extrusion jets located at specified angles to one another inject or meter a narrow stream of a blend of radiopaque powder material and the selected polymer that forms the radiopaque stripes 120 and 125 in the soft tip side wall 145 In the co-extrusion process, one or more radiopaque stripe can be formed that each extend substantially parallel with the axis of the tube and one

another. Alternatively, the distal soft tip tube 170 can be rotated as the co-extrusion takes place to form one or more spiral stripe of the radiopaque material.

FIG. 11 is a perspective view of a distal soft tip tube segment 140 cut from the distal soft tip tube 170 of FIG. 10 with ungular cut sections of the distal soft tip proximal end 155. FIG. 12 is a view of the soft tip proximal end 155 displaying the V-shaped or ungular cut sections. The term "ungular" is derived from the expression "ungula of a right circular cylinder" as defined and illustrated in the Standard Handbook for Mechanical Engineers, Theodore Baumeister, ed., McGraw-Hill Book Co., NY, NY, pp 2--19-20.

As described in the above-incorporated '910 patent, the surface geometry of the proximal end of the soft tip proximal end 155 is modified by first inserting a polymer mandrel (not shown) into the soft tip lumen 150 of a material such as CELCON® acetyl which can be cut easily with a razor blade. A first ungular section 210 of the distal soft tip tube segment 140 is removed by orienting a razor blade at an angle of approximately 30° to the central longitudinal axis and plunge cutting through the soft tip proximal end 155 and the mandrel. A second ungular section 215 of the soft tip tube segment 140 is removed from the soft tip proximal end 155 by orienting and plunge cutting a razor blade 60° to the oblique plane formed by the first cut and 30° to the central longitudinal axis of the soft tip tube segment 140. Angles of less than 30°, for example 15°, create a longer or more pointed, modified soft tip proximal end 155 which increases the surface area for bonding and hence promotes stronger bonds with the distal end of the transition segment 35 or the catheter shaft 30. The polymer mandrel is then removed from the soft tip lumen 150.

The catheter shaft distal end 165 is shaped into two ungular sections having the same that cut angles and dimensions so that the ungular sections of the soft tip proximal end 155 and the catheter shaft distal end 165 can be aligned in a complementary, interlocking orientation, mated together and adhered along the butt weld zone 55 comprising the mutually contacting side walls. FIGs. 13-15 depict these steps of attaching the distal soft tip 40 to the catheter shaft distal end 165.

Again, a CELCON® acetyl polymer mandrel (not shown) is inserted into the catheter lumen 25 to support the catheter shaft side wall 20 adjacent to the catheter shaft distal end 165. First and second ungular sections 225 and 230 are cut into the catheter shaft distal end 165 at the same angles as employed in cutting the ungular sections 210 and 215. In the case described above, a first ungular sections 225 of the catheter shaft distal end 165 is removed by orienting a razor blade at an angle of approximately 30° to the central longitudinal axis and plunge cutting through the catheter shaft 30 and the mandrel. A second ungular section 230 of the catheter shaft distal end 165 is removed by orienting and plunge cutting a razor blade 60° to the oblique plane formed by the first cut and 30° to the central longitudinal axis of the catheter shaft 30. The polymer mandrel is then removed from the catheter lumen 25.

In FIG. 13, the soft tip tube segment 140 and the catheter shaft 30 are assembled prior to bonding by first inserting a TEFLON® coated stainless steel mandrel 175 into the catheter lumen 25 to a depth of approximately 10.0 cm with approximately 5.0 cm extending distal to the catheter shaft distal end 165. The stainless steel mandrel 175 is sized to a sliding fit within catheter shaft lumen 25 and provides rigidity and maintains concentricity for subsequent bonding of the catheter shaft distal end 165 to the soft tip segment proximal end at the butt weld zone 55. The soft tip tube segment 140, is advanced over the distal end of the stainless steel mandrel 175 and rotated to align the ungular cut sections 215 and 220 with the ungular cut sections 225 and 230, respectively, in an interlocking, mating manner as shown in FIG. 13.

There are at least two methods of bonding the ungular cut sections 215 and 220 with the ungular cut sections 225 and 230, respectively. A first method is specifically illustrated in FIG. 14 that involves maintaining a slight spacing between the mating catheter shaft side wall 20 and the distal soft tip tube segment side wall 145 to receive injected polymer material. The spacing is preferably on the order of about 0.1-160.0 mm and preferably 0.5 mm. The assembly is in this way prepared for the bonding operation also illustrated in FIG. 14 and involving the preheating of the

assembled parts of FIG. 13 and the injection of molten material to form a narrow adhesion line or segment 235.

A second method simply involves minimizing the spacing and applying heat and pressure in the presence of a solvent to cause the mating side walls 20 and 145 of the catheter shaft 30 and the soft tip tube segment 140 to melt and adhere together along the butt weld zone.

In the first method illustrated in FIG. 14, the assembly of FIG. 13 is inserted into a mold cavity (not shown) of an injection mold machine such as an Arburg® 221-55-250 with the 0.5 mm spacing is centered over a mold gate. To promote bonding, the assembly of the stainless steel mandrel 175, the soft tip tube segment 140, and the catheter shaft 30 is preheated to a temperature of approximately 130° C. for 90 seconds. A molten shot of Shore 55D PEBAX® polyether block-polyamide material is injected at a nozzle temperature of approximately 265° C. and injection pressure of 500 psi and solidified to form an adhesion segment 235 that is about 0.5 mm wide following the butt weld zone 55. The adhesion segment 235 has inner and outer diameters equaling those of both the catheter shaft 30 and the soft tip tube segment 140. Alter injection molding, the bonded assembly of catheter shaft 30 and the distal soft tip tube segment 140 and the stainless steel mandrel 175 are removed from the mold cavity and cooled to room temperature.

In the second bonding method, the injected polymer 55 is not employed in the process. Instead, the soft tip tube segment 140 and the catheter shaft 30 are assembled prior to bonding the TEFLON® coated stainless steel mandrel 175 as illustrated in FIG. 13 and described above. The ungular cut sections 215 and 220 are brought into mating abutting contact with the ungular cut sections 225 and 230, respectively, in an interlocking, mating manner as shown in FIGs. 13 and 14. A small amount of solvent, e.g., Butanol, is applied along the mating ungular cut edges in the region of the illustrated butt weld zone 55. Then, the assembly is placed in a custom clamp shuttle of an RF welder fitted with a chiller for RF welding of the butt weld zone and for cooling the welded assembly. The assembly is advanced by the shuttle into a die for a

short, e.g., 15 second, cycle of heat and pressure forming, and then the assembly is cooled and the mandrel is removed from the aligned catheter and soft tip lumens.

In FIG. 15, the stainless steel mandrel 175 has been removed from the aligned lumens of the bonded assembly of catheter shaft 30 and the distal soft tip tube segment 140 along butt weld zone 55. Any residual mold gate, runner and sprue remnants are trimmed away, and the distal soft tip 40 is formed by trimming the distal soft tip tube segment 140 to the specified length, e.g., approximately 1.0-1.5 cm distally from the most distally projecting ends of the adhesion segment 235.

FIGs. 16-18 illustrate the steps of fabrication of a catheter body 15 following the first bonding or butt weld method described above having at least one transition segment 35 interposed between the distal soft tip 40 and the catheter shaft 35 as described above. Again, it will be understood that the second bonding or butt weld method can be employed alternatively. The surface geometry of the catheter shaft distal end 165 and the distal soft tip tube segment proximal end 155 are modified as described above to form the catheter ungular sections 240 and 245 and the soft tip ungular sections 215 and 220. In this case, the surface geometry of both the transition segment proximal end 180 and the transition segment distal end 185 are modified in the same manner as the modification of the soft tip proximal end 155 and the catheter shaft distal end 165 described above. The transition segment distal ungular sections 240 and 245 are cut at the same angles as the soft tip ungular sections 215 and 220. Similarly, the transition segment proximal ungular sections 250 and 255 are cut at the same angles as the catheter shaft ungular sections 225 and 230.

In FIG. 16, the soft tip tube segment 140, the transition segment 35, and the catheter shaft 30 are assembled prior to bonding by first inserting a TEFLON® coated stainless steel mandrel 175 into the catheter lumen 25 as described above. The transition segment 35 is advanced over stainless steel mandrel 175 and rotated to align the ungular cut sections 225 and 230 with the ungular cut sections 250 and 255, respectively. Then, the distal soft tip segment 140 is advanced over stainless steel mandrel 175 and rotated to align the ungular cut sections 215 and 220 with the

ungular cut sections 240 and 245, respectively, as shown in FIG. 13. In this alignment, a spacing between the mating catheter shaft side wall 20 and the transition segment side wall 190 is maintained to receive injected polymer material. Similarly, a spacing between distal soft tip tube segment side wall 145 and transition segment side wall 190 is maintained to receive injected polymer material. The spacing is preferably on the order of about 0.1-160.0 mm and preferably 0.5 mm. The assembly is now prepared for the bonding operation.

In FIG. 17, the assembly of FIG. 16 is then inserted into a mold cavity (not shown) of the injection mold machine with the 0.5 mm spacings centered over two, spaced apart, mold gates. As described above, the assembly of the stainless steel mandrel 175, the soft tip tube segment 140, and the catheter shaft 30 is preheated to a temperature of approximately 130° C. for 90 seconds to promote bonding along the butt weld zones 55 and 210. Molten shots of Shore 55D PEBAX® polyether block-polyamide material are injected at the nozzle temperature and injection pressure specified above and solidified to form adhesion segments 235 and 260 that are each about 0.5 mm wide and follow the butt weld zones 55 and 210, respectively. The narrow adhesion segments 235 and 260 have inner and outer diameters equaling those of both the catheter shaft 30 and the soft tip tube segment 140. Alter injection molding, the bonded assembly of catheter shaft 30, the transition segment 35, and the distal soft tip tube segment 140 and the stainless steel mandrel 175 are removed from the mold cavity and cooled to room temperature.

In FIG. 18, the stainless steel mandrel 175 has been removed from the aligned lumens of the bonded assembly of catheter shaft 30, transition segment 35 and distal soft tip tube segment 140 along butt weld zone 55. Any residual mold gate, runner and sprue remnants are trimmed away, and the distal soft tip 40 is formed by trimming the distal soft tip tube segment 140 to the specified length, e.g., approximately 1.0 - 1.5 cm distally from the most distally projecting ends of the adhesion segment 235.

FIG. 19 is a partial side view of the distal end of the catheter of FIGs. 15 and 18 rotated 90°. This view shows that the ungular cuts 215 and 220 (hidden from view in

this figure) bridge the radiopaque stripes 120 and 125 (hidden in view in this figure). It may be preferable to make the ungular cuts at 90° to the angle depicted in FIG. 19. FIG. 20 is a partial side view of the distal end of the catheter of FIGs. 15 and 18 illustrating the alternative manner of making the mating ungular cuts 215' and 220'. This orientation may provide superior adhesion of the soft distal tip 40' to the catheter shaft 30 or transition segment 35. The adhesion segments 235 and 235' may or may not be present depending on the adhesion method employed as described above. The modified surface geometry of the soft tip proximal end 155 and the catheter shaft distal end 165 increases the butt weld zone adhesion surface area and decreases stress concentration along the butt weld zone 55. The use of the interlocking ungular sections results in a surface area 200% greater than the surface area of a simple butt joint. Further, the surface area of the catheter shaft distal end 165 is between 110-200% that of a frustoconical joint. Also, stress concentration which is exhibited by the junctions of the flexible tubular elements of the above-referenced '416 patent, is reduced on the catheter shaft 30 because the oblique planes which define the junction between the catheter shaft 30 and the adhesion segment 235 are not perpendicular to the tensile and flexural loads which are applied to the distal soft tip 40 during use.

The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A medical vascular catheter adapted to be inserted into a blood vessel from an incision through the skin of a patient for introducing other devices or fluids for diagnostic or therapeutic purposes into the patient's vasculature of the type comprising:

an elongated catheter body enclosing a catheter lumen and extending between a catheter body proximal end and a catheter body distal end, the catheter body having a thin catheter body side wall;

a catheter hub formed of a thermoplastic hub material receiving and adhered to a proximal portion of said catheter body in an elongated catheter hub/body junction thereof;

said catheter body further comprising a relatively stiff catheter shaft extending from said catheter hub/body junction to a catheter shaft distal end and a flexible, non-traumatic, distal soft tip attached to the catheter shaft distal end to extend distally therefrom;

said distal soft tip formed of a distal soft tip tube segment having a thin soft tip side wall surrounding a soft tip lumen and extending between a distal soft tip proximal end and a distal soft tip distal end that is cut from an extruded distal soft tip tube; and wherein:

said extruded distal soft tip tube is extruded from a polymer material and incorporates one or more stripe of radiopaque material within said soft tip side wall, said stripe of radiopaque material formed of a radiopaque material blended with the polymer material and co-extruded with the polymer material of the distal soft tip tube, whereby when said extruded soft tip tube is cut into said distal soft tip segment prior to its attachment to the catheter shaft distal end, said one or more stripe of radiopaque material within said soft tip side wall extends generally between said distal soft tip proximal end and said distal soft tip distal end

2. The medical vascular catheter of Claim 1 wherein said catheter shaft distal end and said distal soft tip proximal end are cut into interlocking ungular shapes

extending proximally in the catheter shaft side wall and distally in the soft tip side wall and are attached together by end-to-end mating and adhesion of the respective interlocking ungular shapes to form a butt weld zone.

3. The medical vascular catheter of Claim 1, wherein said one or more radiopaque stripe co-extruded in said soft tip side wall extends substantially in parallel with said soft tip lumen between said distal soft tip proximal end and said distal soft tip distal end.

4. The medical vascular catheter of Claim 1, wherein said one or more radiopaque stripe co-extruded in said soft tip side wall extends in a spiral around said soft tip side wall between said distal soft tip proximal end and said distal soft tip distal end.

5. The medical vascular catheter of Claim 1, wherein:

said extruded distal soft tip tube further comprises a soft tip lumen surface and a soft tip outer tube surface formed by tubular extrusion of said soft tip side wall from polymer material; and

each radiopaque stripe co-extruded in said soft tip lumen side wall is embedded within the polymer that forms the soft tip lumen surface and the soft tip outer tube surface, so that the radiopaque material is substantially encased in the polymer material to provide smooth soft tip lumen and outer tube surfaces.

6. The medical vascular catheter of Claim 5, wherein the embedded radiopaque stripe has a stripe cross-section that is substantially circular.

7. The medical vascular catheter of Claim 5, wherein the embedded radiopaque stripe has a stripe cross-section that is substantially arcuate.

8. The medical vascular catheter of Claim 1, wherein:

said extruded distal soft tip tube further comprises a soft tip lumen surface and a soft tip outer tube surface formed by tubular extrusion of said soft tip side wall from polymer material; and

each radiopaque stripe co-extruded in said soft tip lumen side wall extends between the soft tip lumen surface and the soft tip outer tube surface.

9. The medical vascular catheter of Claim 8, wherein the embedded radiopaque stripe has a stripe cross-section that is substantially circular.

10. The medical vascular catheter of Claim 8, wherein the embedded radiopaque stripe has a stripe cross-section that is substantially arcuate.

11. The medical vascular catheter of Claim 1, wherein:

said extruded distal soft tip tube further comprises a soft tip lumen surface and a soft tip outer tube surface formed by tubular extrusion of said soft tip side wall from polymer material; and

each radiopaque stripe co-extruded in said soft tip lumen side wall extends from the soft tip lumen surface and into the side wall toward but not reaching the soft tip outer tube surface.

12. The medical vascular catheter of Claim 1, wherein:

said extruded distal soft tip tube further comprises a soft tip lumen surface and a soft tip outer tube surface formed by tubular extrusion of said soft tip side wall from polymer material; and

each radiopaque stripe co-extruded in said soft tip lumen side wall extends from the soft tip outer tube surface and into the side wall toward but not reaching the soft tip lumen surface.

13. The medical vascular catheter of Claim 1 wherein:

said catheter body further comprises a high tensile strength, transition segment having a proximal transition segment end attached to the catheter shaft distal end and a transition segment distal end; and

said distal soft tip proximal end is attached to the transition segment distal end.

14. The medical vascular catheter of Claim 13, wherein said transition segment distal end and said distal soft tip proximal end are cut into interlocking ungular shapes extending proximally in the transition segment side wall and distally in the soft tip side wall and are attached together by end-to-end mating and adhesion of the respective interlocking ungular shapes to form a butt weld zone.

15. The medical vascular catheter of Claim 1, wherein said extruded distal soft tip tube is extruded from a first blend of a polymer material with a radiopaque material forming the entire side wall of the extruded distal soft tip tube so that the entire distal soft tip exhibits faint radiopacity when viewed under fluoroscopy and said one or more radiopaque stripes are co-extruded with a second blend of a polymer material and a radiopaque material having a greater radiopacity than said faint radiopacity so that the radiopaque stripes can be seen within the faint radiopaque image of the soft distal tip.

16. A method of fabricating a distal soft tip at the distal end of a catheter body of a vascular catheter adapted to be inserted into a blood vessel from an incision through the skin of a patient for introducing other devices or fluids for diagnostic or therapeutic purposes into the patient's vasculature, the method comprising the steps of:

fabricating a catheter shaft surrounding a catheter lumen and extending between a catheter body proximal end and a catheter shaft distal end, the catheter shaft having a thin catheter shaft side wall;

extruding a distal soft tip tube of a polymer material having a thin soft tip side wall surrounding a soft tip lumen;

co-extruding one or more stripe of radiopaque material within said soft tip side wall, said stripe of radiopaque material formed of a radiopaque material blended with the polymer material and co-extruded with the polymer material of the distal soft tip tube;

cutting the distal soft tip tube into a distal soft tip tube segment having a distal soft tip proximal end and a distal soft tip distal end, whereby said one or more stripe of radiopaque material within said soft tip side wall extends generally between said distal soft tip proximal end and said distal soft tip distal end; and

bonding the distal soft tip tube proximal end and the catheter shaft distal end together.

17. The method of Claim 16, wherein said co-extruding step further comprises the step of co-extruding said one or more radiopaque stripe in said soft tip side wall to extend substantially in parallel with said soft tip lumen between said distal soft tip proximal end and said distal soft tip distal end.

18. The method of Claim 16 further comprising the step of:

modifying the surface geometry of the distal soft tip proximal end and the catheter shaft distal end to increase the surface area for bonding.

19. The method of Claim 17, wherein:

the step of modifying the surface geometry of the distal soft tip proximal end and the catheter shaft distal end to increase the surface area for bonding comprises forming said catheter shaft distal end and said distal soft tip proximal end into interlocking ungular shapes extending proximally in the catheter shaft side wall and distally in the soft tip side wall; and

the bonding step further comprises the steps of:

aligning the respective interlocking ungular shapes end-to-end to form a butt weld zone; and

adhering the interlocking ungular shapes together mated surfaces in the butt weld zone.

20. The method of Claim 16, wherein said co-extruding step further comprises the step of co-extruding said one or more radiopaque stripe co-extruded in said soft tip side wall extends in a spiral around said soft tip side wall between said distal soft tip proximal end and said distal soft tip distal end.

21. The method of Claim 16 further comprising the steps of:

providing a transition segment shaft surrounding a transition segment lumen and extending between a transition segment proximal end and a transition segment distal end, the transition segment shaft having a thin and relatively more flexible transition segment side wall than said relatively stiff catheter shaft side wall;

bonding the catheter shaft distal end and the transition segment proximal end together; and

bonding the distal soft tip tube proximal end and the transition segment distal end together.

22. The method of Claim 21 further comprising the step of:

modifying the surface geometry of the distal soft tip proximal end and the transition segment distal end to increase the surface area for bonding.

23. The method of Claim 21, wherein:

the step of modifying the surface geometry of the distal soft tip proximal end and the transition segment distal end to increase the surface area for bonding comprises forming said transition segment distal end and said distal soft tip proximal end into interlocking ungular shapes extending proximally in the catheter shaft side wall and distally in the soft tip side wall; and

the bonding step further comprises the steps of:

aligning the respective interlocking ungular shapes end-to-end to form a butt weld zone; and

adhering the interlocking ungular shapes together mated surfaces in the butt weld zone.

24. The method of Claim 16, wherein said co-extruding step further comprises the step of co-extruding said one or more radiopaque stripe in said soft tip side wall in a substantially circular cross-section embedded within the polymer that forms the soft tip lumen surface and the soft tip outer tube surface, so that the radiopaque material is substantially encased in the polymer material to provide smooth soft tip lumen and outer tube surfaces.

25. The method of Claim 16, wherein said co-extruding step further comprises the step of co-extruding said one or more radiopaque stripe in said soft tip side wall in a substantially arcuate cross-section embedded within the polymer that forms the soft tip lumen surface and the soft tip outer tube surface, so that the radiopaque material is substantially encased in the polymer material to provide smooth soft tip lumen and outer tube surfaces.

26. The method of Claim 16, wherein said co-extruding step further comprises the step of co-extruding said one or more radiopaque stripe in said soft tip side wall in a substantially circular cross-section and extending between the soft tip lumen surface and the soft tip outer tube surface.

27. The method of Claim 16, wherein said co-extruding step further comprises the step of co-extruding said one or more radiopaque stripe in said soft tip side wall in a substantially arcuate cross-section extending between the soft tip lumen surface and the soft tip outer tube surface.

28. The method of Claim 16, wherein said co-extruding step further comprises the step of co-extruding said one or more radiopaque stripe in said soft tip side wall extending from the soft tip lumen surface and toward the soft tip outer tube surface a predetermined distance so that the radiopaque material is substantially encased in the polymer material to provide a smooth outer tube surface.

29. The method of Claim 16, wherein said co-extruding step further comprises the step of co-extruding said one or more radiopaque stripe in said soft tip side wall extending from the soft tip outer tube surface and toward the soft tip lumen surface a predetermined distance so that the radiopaque material is substantially encased in the polymer material to provide a smooth soft tip lumen surface.

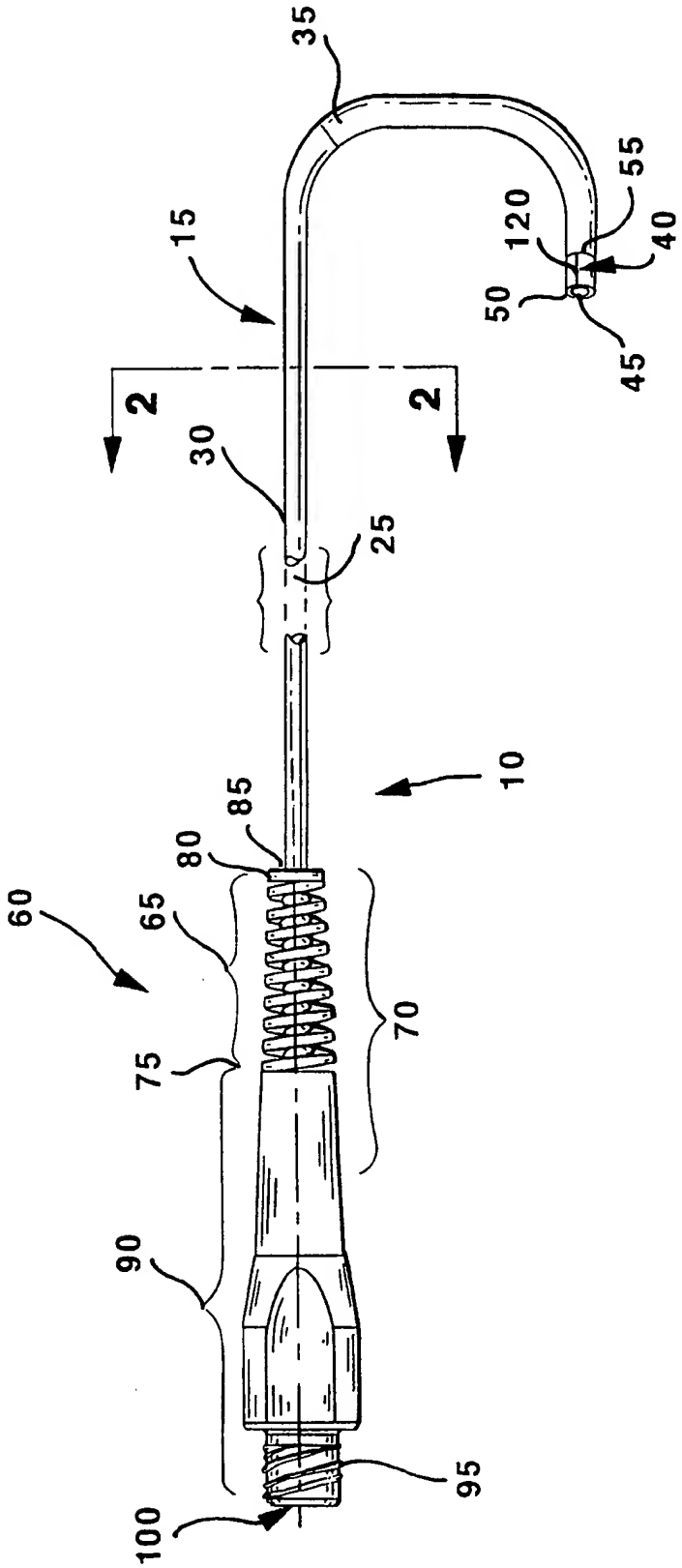

FIG.1

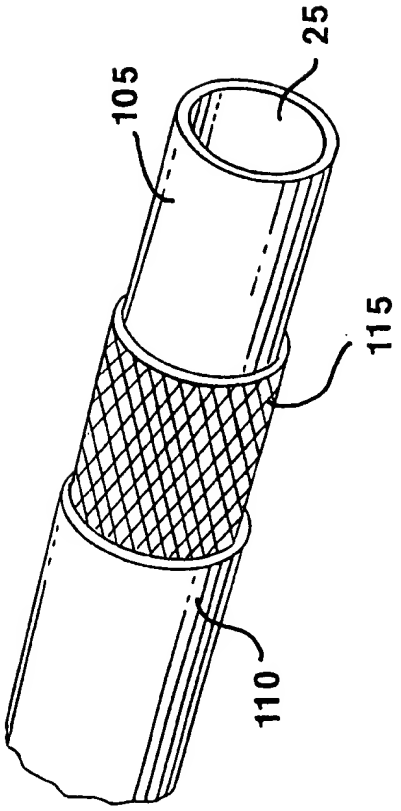

FIG.3

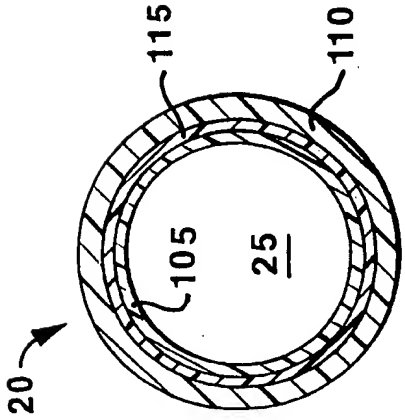

FIG.2

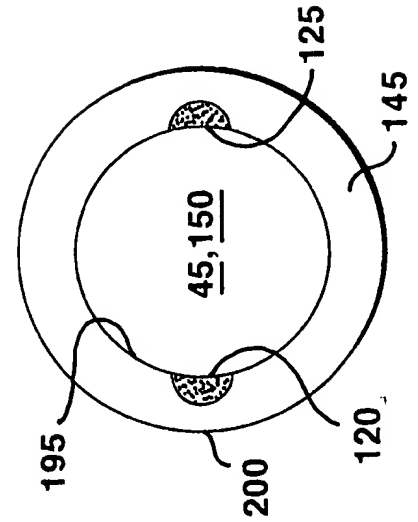

FIG.6

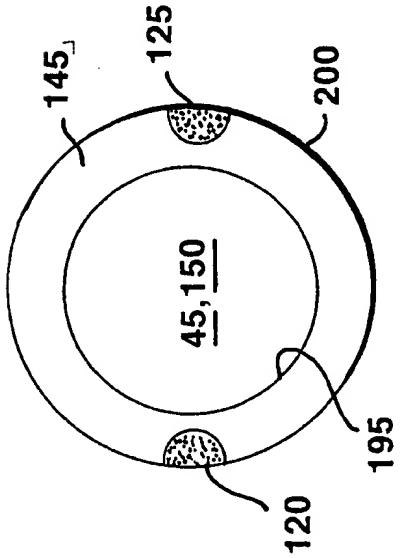

FIG.5

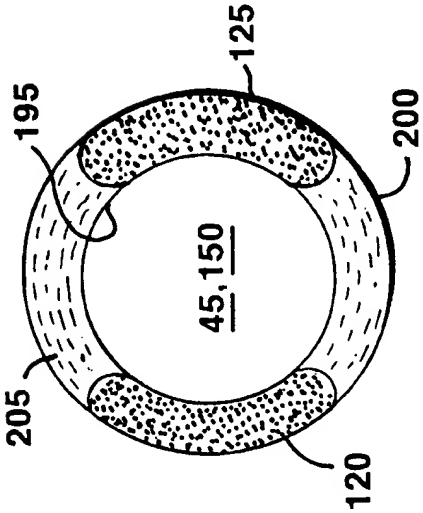

FIG.4

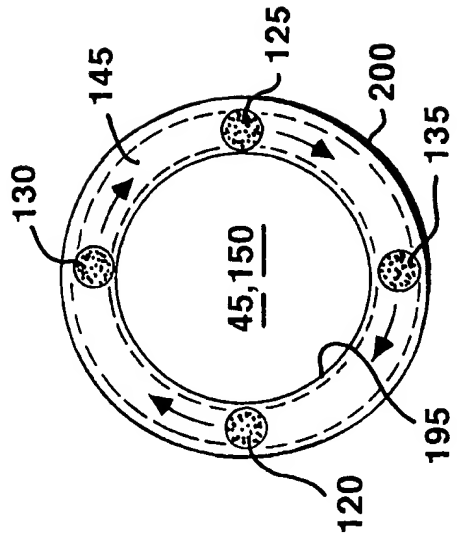

FIG.9

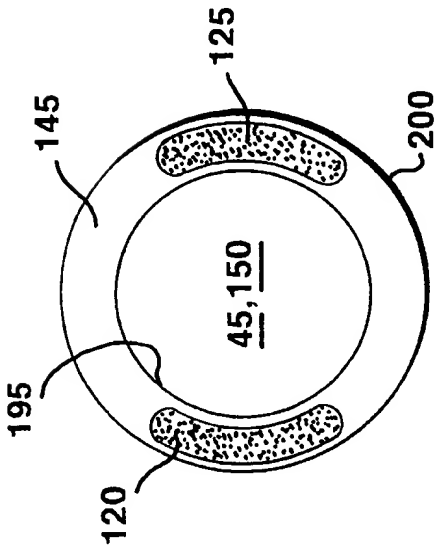

FIG.8

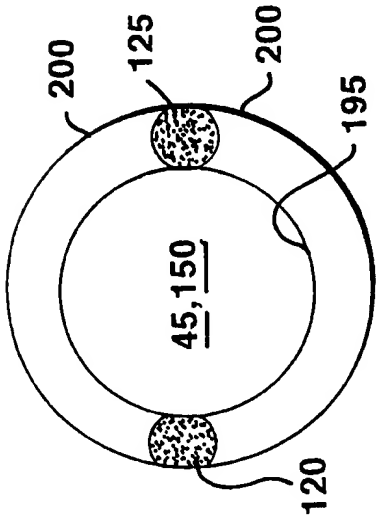

FIG.7

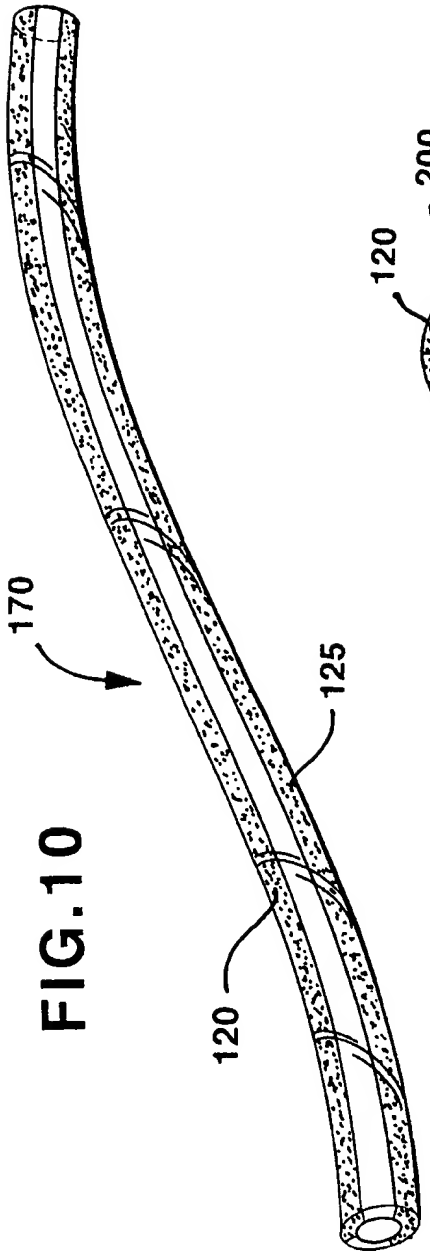

FIG.10

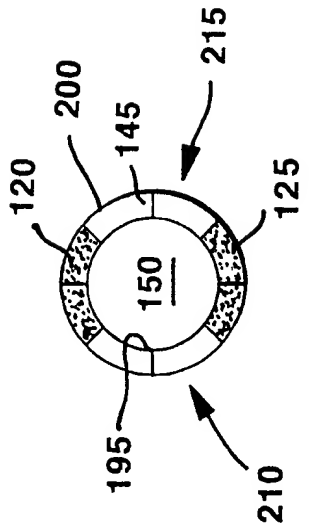

FIG.12

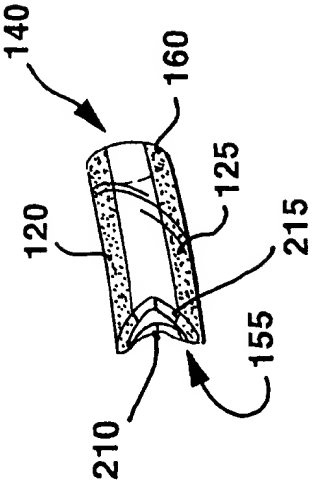

FIG.11

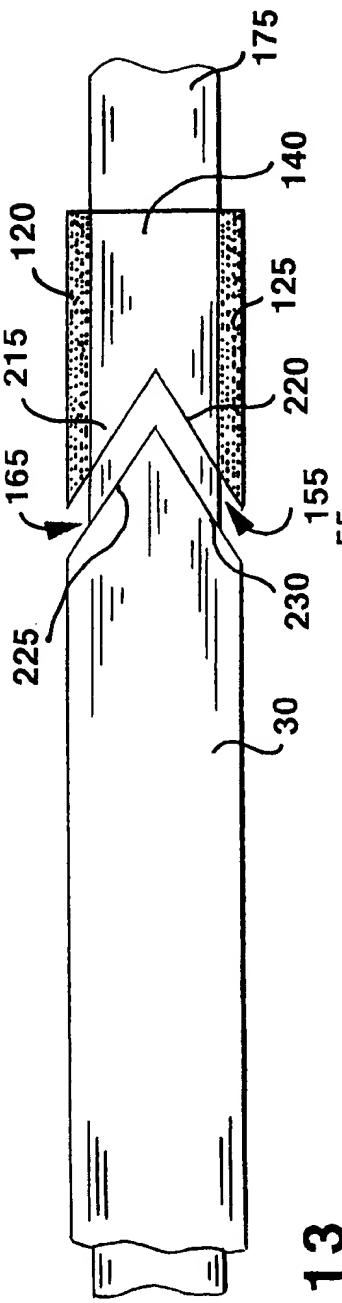

FIG.13

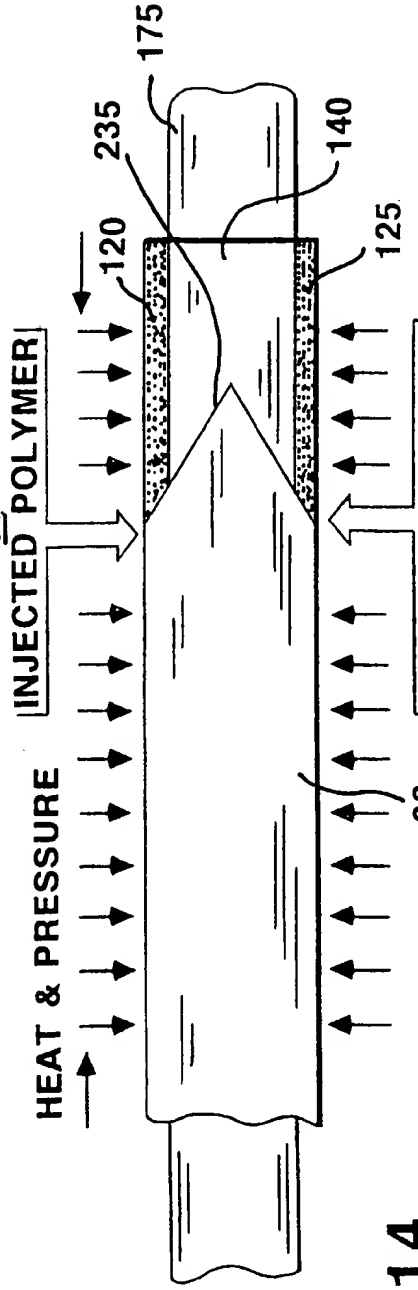

FIG.14

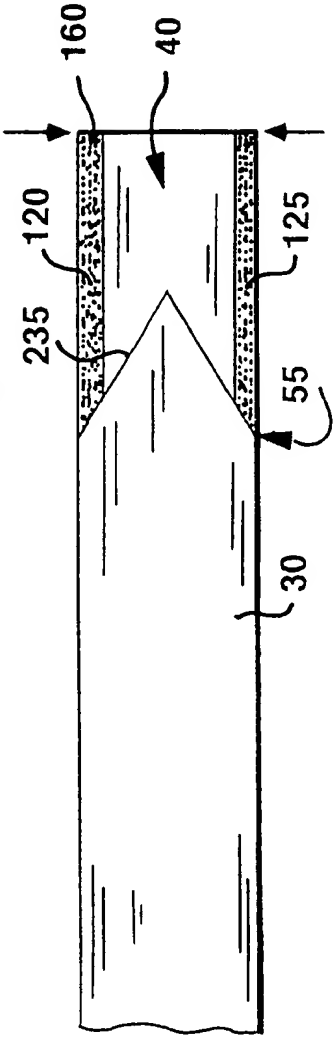

FIG.15

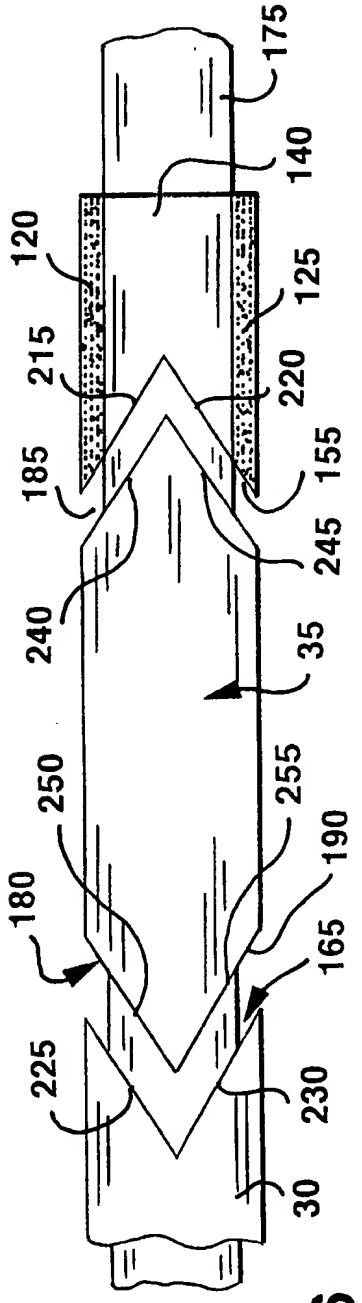

FIG.16

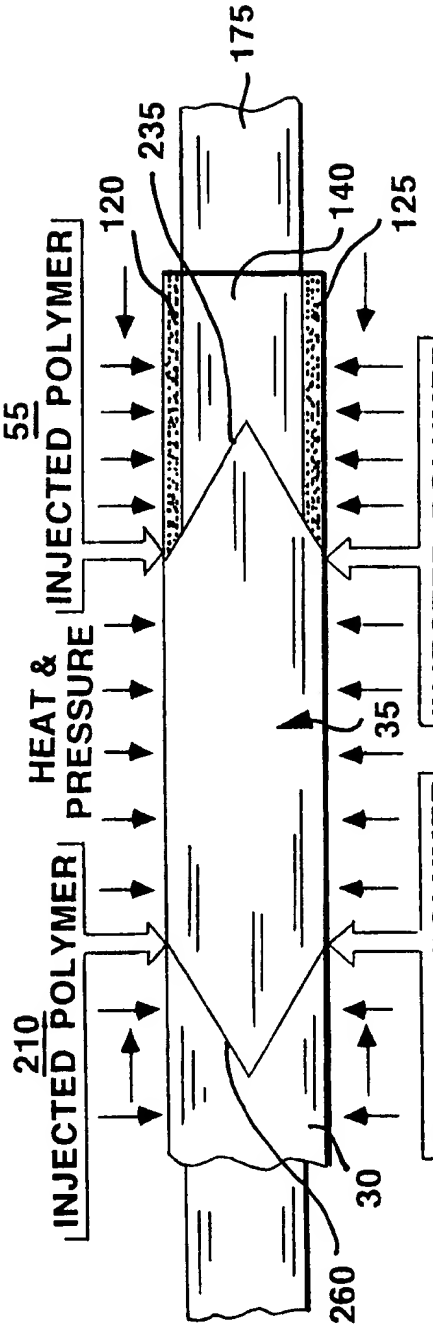

FIG.17

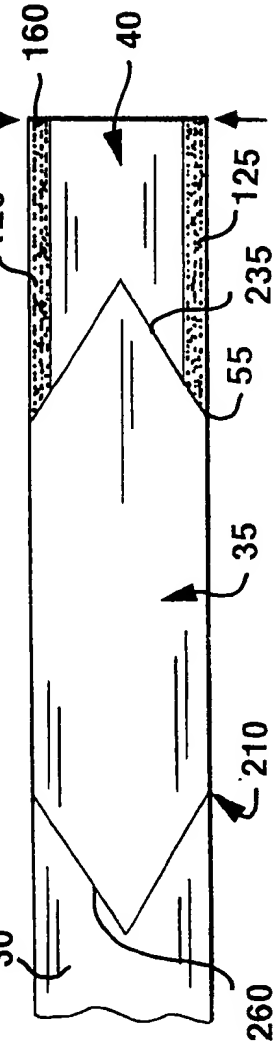

FIG.18

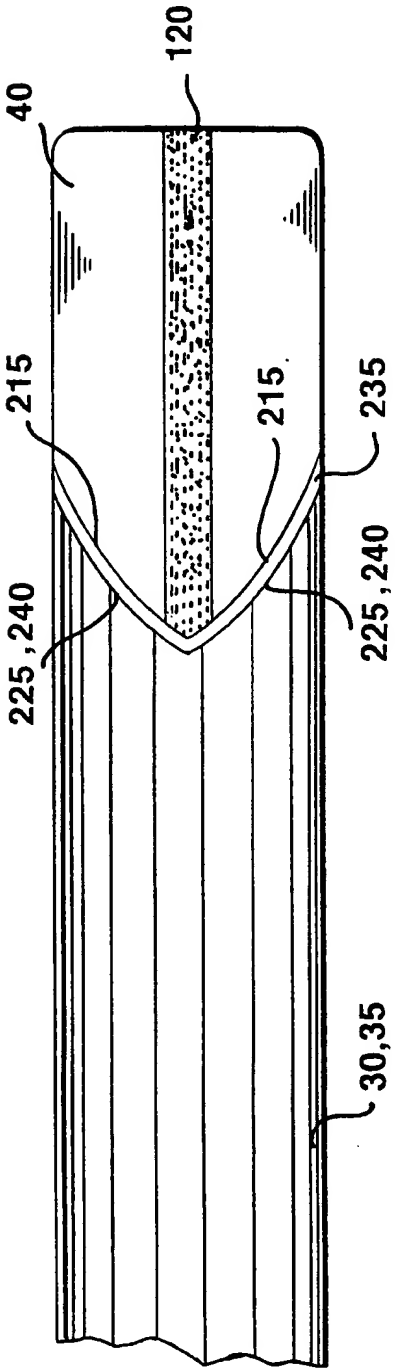
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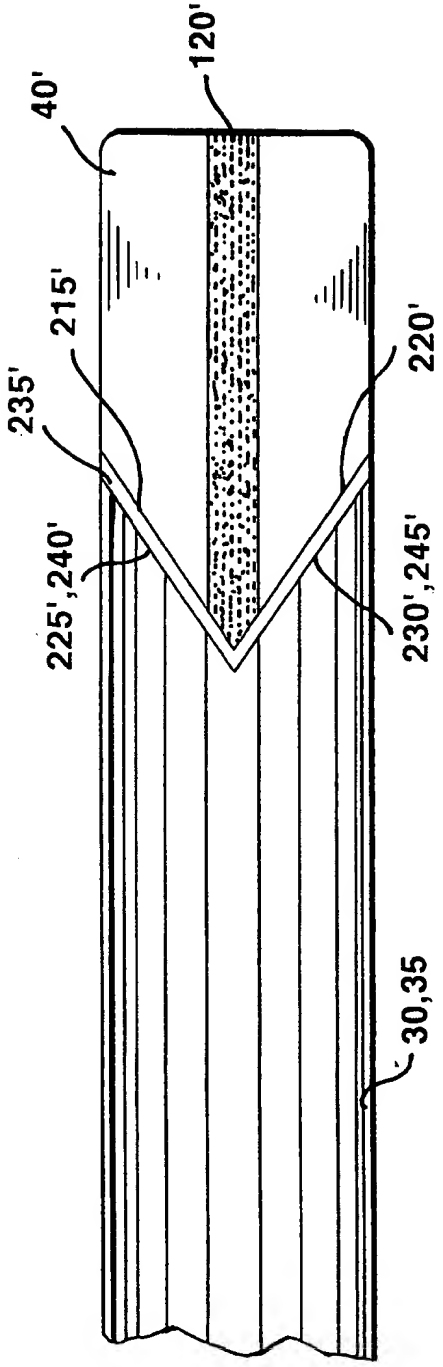
FIG.19


40'
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225',240'
230',245'
30,35

FIG.20

INTERNATIONAL SEARCH REPORT

Inter. nal Application No
PCT/US 99/03876

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/00 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 040 508 A (SHILEY INCORPORATED) 25 November 1981 see page 3, line 13 - page 5, line 14 see figures 1,2 ---	1,3,5-7, 16-18, 24,25
Y	WO 82 00413 A (ABBOTT LABORATORIES) 18 February 1982 see page 3, line 27 - page 5, line 26 see figures 1-7 ---	1,3,5-7, 16-18, 24,25
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A	US 5 429 617 A (HAMMERSMARK ET AL.) 4 July 1995 cited in the application see column 2, line 14 - line 22 see column 4, line 54 - column 5, line 10 --- -/--	1,16

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 July 1999	09/07/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Schönleben, J

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INTERNATIONAL SEARCH REPORT

Intern .ial Application No
PCT/US 99/03876

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate. of the relevant passages	Relevant to claim No.
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A	US 4 469 483 A (BECKER ET AL.) 4 September 1984 see column 3, line 25 - column 4, line 60 see figure 1	8-10,26, 27
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A	DE 89 05 642 U (REHAU AG & CO) 10 August 1989 see claim 1 see figure 1	1,16
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. nal Application No
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